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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yoshiharu Uehata

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EXAMINER

SELKIN, SAUREL J

ART UNIT

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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,523	Applicant(s) UEHATA ET AL.	
	Examiner SAUREL J. SELKIN	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/01/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1, 2, 3, 4, 5, 6, 7, 8, 19, 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Garthe et al (US 2003/0225429 henceforth referred to as Garthe).

Garthe discloses a lancing apparatus comprising a lancet holder movable in a lancing direction from a standby position and including a first 40 and second 60 member movable relative to each other so that the main body of a lancet held therein can be removed from the lancet holder, fixing means that applies a fixing force on the lancet in the fixing position, engaging means 41, 52 for engaging the first and second members to each other wherein at least one of the engaging portions project toward the other one engaging portion comprising a recess 52 and the other a projection 41 to be fitted into the recess and either the first or second members applies a pressing force to a lancet for fixing it wherein when the holder is being loaded the lancet moves relative to a first member while the second member moves with the lancet relative to the first member and the lancet holder is capable of applying a greater force on the lancet when the second member is located and the first member includes a first pressing portion which applied a force upon the lancet said pressing portion being at least partially displaced

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form the lance as it moved away from the fixing position (fig. 4, fig. 5, abstract, [0013], [0014], [0031]). Garthe also discloses a pushing member for moving the second member in the lancing direction wherein the pushing member comprised a portion that interferes with the second member causing it to move it the lancing position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 9, 16, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama et al. (US 6,039,485, henceforth referred as Kageyama).

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Garthe discloses the apparatus substantially as claimed but fails to disclose a pair of movable portions wherein a gap is provided between the moving portions.

Although Garthe fails to explicitly disclose a portion for engaging a lancet, one having ordinary skill in the art would recognize that such a portion would be provide since the device is capable of moving without the lance held therein being dislodged from it.

Kageyama discloses a dispenser comprising members movable relative to each other (figure 10 and 12 (34), (26)) that apply pressing force to holds a lead in between (column 1, lines 36-45) for advancing and retracting the lead. Although this invention is used to hold the lead, however this holding mechanism of Kageyama's invention is capable of holding a lancet and advancing and retracting the lancet. The holder applies greater pressing force due to the movement of relative moving members. The holding space between holding members decreases as they moves relative to each other, which results in pressing and holding, as it said, "The size of the gap "d" further decreases to reliably tighten the lead when the tip chuck 34 moves backward to its rear-most position, into the tip fitting 12" (column 10, lines 20-22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's apparatus by providing a holding mechanism as taught by Kageyama so as to enhance the lancet holder's ability to firmly hold the lancet when moving it back and forth.

Concerning claims 16 and 17, Kageyama discloses an invention comprises of two movable members. The gap between these members changes as they move relative to each other (column 10, lines 20-24). The distance between these two

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members decreases when one member move in retreating direction with respect to other member (column 10, line 20) and vice versa.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's apparatus by providing a lancet-holding mechanism as taught by Kageyama so as to obtain efficient loading and unloading of the lancet.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama as applied to claim 9 above, and further in view of Okumura et al. (US 6,226,873, henceforth referred to as Okumura).

The Garthe and Kageyama combination discloses the apparatus substantially as claimed but fails to disclose that lancet holding mechanism contains cutaway portions.

Okumura discloses an apparatus comprising of movable portions, which includes cutaway (figure 1, (lb)). The working portion fits into the cutaway (figure 1 and column 1, lines 52-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe and Kageyama combination by providing a cutaway portion as taught by Okumura in order to improve the device's locking capability.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama and Okumura as applied to claim 10 above, and further in view of Searle et al (US 2002/0087180, henceforth referred to as Searle).

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The Garthe, Kageyama and Okumura combination discloses the apparatus substantially as claimed but fails to disclose a cutaway comprising a first cutaway portion into which a working portion is fitted.

Searle discloses an invention, which contains first cutaway portion into which working portion (figure 7, (26), (46)) is fitted in fixing the lancet (figure 7) and second cutaway portion into which working portion is fitted in discharging the lancet (figure 9).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe, Kageyama and Okumura combination by providing a cutaway portion as taught by Searle so as to have better control in locking the lancet.

5. Claims 12, 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama and Okumura as applied to claim 10 above, and further in view of Ritson et al. (US 5,041,088, henceforth referred to as Ritson).

The Garthe, Kageyama and Okumura combination discloses the apparatus substantially as claimed but fails to disclose a cutaway portion arranged to make a gap continuously or incrementally narrower.

Ritson discloses a lancing apparatus that contains a stepped portion for change in gap (column 4, lines 36-43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe, Kageyama and Okumura combination

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by providing a step portion for change in the diameter of holding mechanism as taught by Ritson so as to have rapid fixation of the lancet.

Response to Arguments

6. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAUREL J. SELKIN whose telephone number is

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(571)270-3813. The examiner can normally be reached on Monday-Thursday 7:00 a.m.- 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. S./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768